

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jia-Hwa Fang et al.
Application No.: Unassigned
Date Filed: Filed Herewith
Title: MICROPARTICLE COMPOSITIONS AND METHODS FOR THE
MANUFACTURE THEREOF
Group Art: 1615
Examiner: Unassigned
Docket: PP16502.015

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Patent
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22231-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☐ A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☒ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number
09/967,462

U.S. Filing Date
09/28/2001

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

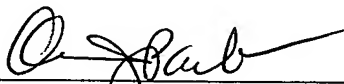
FEES

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. ☒ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
 - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
 - c. ☐ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
 - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
 - b. ☐ See the statement below. No fee is required.
- VI. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):
on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
 - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)
The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
 - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
 - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- ☐ A check in the amount of _____ is enclosed for the above-identified fee(s).
 - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
 - ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
 - ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,
Mayer Fortkort & Williams, PC



Keum J. Park
Attorney for Applicant
Reg. No. 42,059
Tel. 908-518-7700

Mayer Fortkort & Williams, PC
Customer Number 27774

Enclosures: ☒ PTO/SB/08
☐ References
☐ Foreign Search Report
☐ Other:

Certificate of Mailing By Express Mail

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Mail Stop Patent, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on 2/10/04.

Marjorie Scariati
(Printed name of Person Mailing Correspondence)

Marjorie Scariati
(Signature)

Please type a plus sign (+) inside this box. FORM PTO/SB/08

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	Unassigned
				Filing Date	Filed Herewith
				First Named Inventor	Jia-Hwa Fang et al.
				Group Art Unit	1615
Sheet	1	of	4	Examiner Name	Unassigned
				Attorney Docket Number	PP16502.015

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
	1	5,538,739	424/501	Bodmer et al.	07-1996
	2	5,643,605	424/489	Cleland et al.	07-1997
	3	US 2002/0009468	424/252.1	Brayden	01-2002
	4	5,783,567	514/44	Hedley et al.	07-21-1998
	5	5,869,103	424/501	Yeh et al.	02-09-1999
	6	5,871,747	424/208.1	Gengoux-Sedlik et al.	02-16-1999
	7	3,523,907	252/316	Vrancken et al.	08-11-1970
	8	5,814,482	435/69.3	Dubensky Jr. et al.	09-29-1998
	9	5,842,723	285/49	Hartling et al.	12-01-1998
	10	5,928,647	424/196.11	Rock	07-27-1999
	11	6,015,686	435/69.1	Dubensky Jr. et al.	01-18-2000
	12	6,086,901	424/283.1	O'Hagan et al.	07-11-2000

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office ³	Number	Class/Subclass			
	1	WO	01/81609 A2	C12N 15 86		01-11-2001	X
	2	WO	94/28879	A61K 9		12-22-1994	X
	3	WO	95/24929	A61K 48		09-21-1995	X
	4	WO	96/20698	A61K 9		07-11-1996	X
	5	WO	97/02810	A61K 9		01-30-1997	X
	6	WO	98/10750	A61K 9		03-19-1998	X
	7	WO	90/14837	A61K 37 10		12-13-1990	X
	8	WO	94/15635	A61K 39 385		07-21-1994	X
	9	WO	97/38087	C12N		10-16-1997	X
	10	WO	98/33487	A61K 9 16		08-06-1998	X
	11	WO	99/18226	C12N 15 86		04-15-1999	X
	12	WO	00/06123	A61K 9 16		02-10-2000	X
Examiner Signature					Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Unassigned
				Filing Date	Filed Herewith
				First Named Inventor	Jia-Hwa Fang et al.
				Group Art Unit	1615
				Examiner Name	Unassigned
Sheet	2	of	4	Attorney Docket Number	PP16502.015

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY
		Number	Class/Subclass		

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office ³	Number	Class/ Subclass			
	13	WO	00/50006	A61K 9 107		08-31-2000	X
	14	WO	01/36599	C12N 5 06		05-25-2001	X
Examiner Signature					Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known	
				Application Number	Unassigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	Filed Herewith
				First Named Inventor	Jia-Hwa Fang et al.
				Group Art Unit	1615
				Examiner Name	Unassigned
(use as many sheets as necessary)				Attorney Docket Number	PP16502.015
Sheet	3	of	4		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Kazzaz, J. et al., "Induction of Cytotoxic T-lymphocyte activity in mice with HIV p24 gag protein adsorbed to the surface of poly(lactide-co-glycolide) microparticles," Proceed. Int'l Symp. Control. Rel. Bioact. Mater., 26 (1999), Controlled Release Society, pp. 104-105.	X
	2	Coombes, A.G.A. et al., "Single Does, Polymeric, Microparticle-Based Vaccines: The Influence of Formulation Conditions On The Magnitude and Duration of the Immune Response To A Protein Antigen," Vaccine, Vol. 14, No. 15, 1996, pp. 1429-1438.	X
	3	Duncan, J.D. et al., "Poly(lactide-co-glycolide) Microencapsulation of Vaccines For Mucosal Immunization," Mucosal Vaccines, 1996, pp. 159-173.	X
	4	Eldridge, J. et al., "New Advances In Vaccine Delivery Systems," Seminars in Hematology, Vol. 30, No. 4, Suppl. 4, Oct. 1993, pp. 16-25.	X
	5	Higgins, D. et al., "MF59 Adjuvant Enhances the Immunogenicity of Influenza Vaccine in Both Young and Old Mice," Vaccine, Vol. 14, No. 6, 1996, pp. 478-484.	X
	6	Men, Y. et al., "Introduction of a Cytotoxic T Lymphocyte Response By Immunization With A Malaria Specific CTL Peptide Entrapped In Biodegradable Polymer Microspheres," Vaccine, Vol. 15, No. 12/13, 1997, pp. 1405-1412.	X
	7	Moore, A. et al., "Immunization With A Soluble Recombinant HIV Protein Entrapped In Biodegradable Microparticles Induces HIV-Specific CD8+ Cytotoxic T Lymphocytes And CD4+ TH1 Cells," Vaccine, Vol. 13, No. 18, 1995, pp. 1741-1995.	X
	8	Nakaoka, R. et al., "Enhanced Antibody Production Through Sustained Antigen Release From Biodegradable Granules," Journal of Controlled Release, Vol. 37 (1995), pp. 215-224.	X
	9	O'Hagan, Derek et al., "Biodegradable Microparticles for Oral Immunization, Vaccine, Vol. 11, 1993, pp. 149-154.	
	10	O'Hagan, Derek et al., "Long-Term Antibody Responses In Mice Following Subcutaneous Immunization With Ovalbumin Entrapped In Biodegradable Microparticles," Vaccine, Vol. 11, 1993, pp. 1965-1969.	
	11	Sah, H. et al., "Continuous Release of Proteins From Biodegradable Microcapsules and In Vivo Evaluation of Their Potential As A Vaccine Adjuvant," Journal of Controlled Release 35 (1995), pp.137-144.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO				Complete if Known	
				Application Number	Unassigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	Filed Herewith
				First Named Inventor	Jia-Hwa Fang et al.
				Group Art Unit	1615
				Examiner Name	Unassigned
(use as many sheets as necessary)				Attorney Docket Number	PP16502.015
Sheet	4	of	4		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	12	Vordermeier, H.M. et al., "Synthetic Delivery System For Tuberculosis Vaccines: Immunological Evaluation of the M. Tuberculosis 38 kDa Protein Entrapped In Biodegradable PLG Microparticles," Vaccine, Vol. 13, No. 16, 1995, pp. 1576-1582.	X
	13	Powell, M. F. et al., "Vaccine Design: The Subunit And Adjuvant Approach," Plenum Press, New York, 1995, p.183.	X
	14	Eldridge, J. et al., "Biodegradable and Biocompatible Poly(DL-Lactide-Co-Glycolide) Microspheres As An Adjuvant For Staphylococcal Enterotoxin B Toxoid Which Enhances The Level Of Toxin-Neutralizing Antibodies," Infection and Immunity, Vol. 59, No. 9, Sept. 1991, pp. 2978-2986.	X
	15	Singh, Manmohan et al., "The preparation and characterization of polymeric antigen delivery systems for oral administration," Advanced Drug Delivery Reviews 34 (1998), pp. 285-304.	X
	16	Denis-Mize, K.S. et al., "Plasmid DNA Adsorbed onto cationic microparticles mediates target gene expression and antigen presentation by dendritic cells," Gene Therapy 2000, pp. 2105-2112.	X
	17	Kazzaz, J. et al., "Novel anionic microparticles are a potent adjuvant for the induction of cytotoxic T lymphocytes against recombinant p55 from HIV-1," Journal of Controlled Release 67 (2000), pp. 347-356.	X
	18	Singh, Manmohan et al., "Cationic microparticles: A potent delivery system for DNA vaccines," Proceedings of the National Academy of Science, January 18, 2000, Vol. 97, No. 2, pp. 811-816.	X
	19	O'Hagan, Derek T., et al., "Long-term antibody responses in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," Vaccine, Vol. 11, Issue 9, 1993, pp. 965-969.	X
	20	Hayley, Jeffery et al., "The preparation and Characterization of Poly(lactide-co-glycolide) Microparticles. II. The Entrapment of a Model Protein Using a (Water-in-Oil)-in-Water Emulsion Solvent Evaporation Technique," Pharmaceutical Research, Vol. 10, No. 3, 1993, pp. 362-368.	X
	21	Ogawa, Yasuaki et al., "A New Technique To Efficiently Entrap Leuprolide Acetate Into Microcapsules of Polylactic Acid or Copoly (Lactic/Glycolic) Acid," Chem. Pharm. Bull., Vol. 36, 1988, pp. 1095-1103.	X
	22	Polo, John M. et al., "Stable alphavirus packaging cell lines for Sindbis virus-and Semliki Forest virus-derived vectors," Proceedings of the National Academy of Science, Vol. 96, April 1999, pp. 4598-4603.	X
	23	Chapman, Barbara S., "effect of intron A from human cytomegalovirus (Towne) immediate-early gene on heterologous expression in mammalian cells," Nucleic Acids Research, Vol. 19, No. 14, pp. 3979-3986.	X
Examiner Signature			Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.